

REMARKS

Claims 1 and 4-22 are pending in this application. Claims 1, 4, 11 and 19 have been amended. Claim 3 has been canceled and its limitations have been incorporated in amended independent claim 1. No new matter has been introduced and no new issues have been raised.

Claims 1 and 4-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lizardi (U.S. Patent No. 5,944,724) in view of Keane (U.S. Patent Publ. No. 2003/0204195). This rejection is respectfully traversed.

The claimed invention relates to a suture storing device and method of dispensing suture. Amended independent claim 1 recites a "suture storing device" comprising "an elongated shaft having a longitudinal axis, a proximal end and a distal end" and "a handle provided at the proximal end." Amended independent claim 1 also recites "a cavity within the handle for storing at least one strand of suture, wherein the cavity is provided with a hatch, the hatch having a tie-down bar attached to its inside." Amended independent claim 1 further recites that the hatch is "configured to pivot, together with the tie-down bar on its inside, relative to the longitudinal axis of the elongated shaft."

Amended independent claim 11 recites a "device for housing sutures attached to surgical needles" comprising "an elongated shaft having a longitudinal axis, a proximal end and a distal end" and "a handle provided at the proximal end." Amended independent claim 11 also recites "a cavity within the handle for storing at least one strand of suture provided with at least one surgical needle, the cavity being provided with a pivotable hatch, the pivotable hatch having a tie-down bar attached on its inside, the pivotable hatch being configured to pivot, together with the tie-down bar

on its inside, relative to the longitudinal axis of the elongated shaft, wherein the tie-down bar is further provided with a slot for storing the at least one surgical needle.”

Amended independent claim 19 recites a “method of dispensing a surgical suture” by *inter alia* “providing a suture housing device comprising . . . a handle provided at the proximal end; and a cavity adjacent the handle for storing at least one strand of suture, the cavity being provided with a pivotable hatch, the pivotable hatch having a tie-down bar attached on its inside, the pivotable hatch being configured to pivot, together with the tie-down bar on its inside, relative to the longitudinal axis of the shaft, the pivotable hatch being integral with the handle when the pivotable hatch is in a closed position, and wherein the surgical suture is coiled around the tie-down bar.” Amended independent claim 19 also recites “actuating the pivotable hatch so that the pivotable hatch forms an angle with respect to the longitudinal axis of the elongated shaft” and “deploying the surgical suture from around the tie-down bar.”

Lizardi relates to a “system for inserting suture anchors” that includes “a suture anchor insertion tool, a suture anchor, a length of suture thread and any needles pre-attached thereto.” (Abstract). Lizardi teaches that the suture anchor insertion tool has “a handle, an elongate suture anchor inserting member, a suture thread retaining cap provided on the handle, an internal retaining cavity formed integrally with the handle and a cover member that is selectively positionable so as to enclose the internal cavity.” (Abstract).

Keane relates to “[D]evices for dispensing suture threads and/or suture threads with needles attached to them that are particularly useful for inserting surgical implants, such as suture anchors, that make use of sutures.” (Abstract). According to Keane, the devices use “a novel spool design to safely and neatly hold the suture thread and/or needles until the surgeon wishes to dispense them.” (Abstract).

The subject matter of claims 1 and 4-22 would not have been obvious over Lizardi and Keane. Specifically, the Office Action fails to establish a *prima facie* case of obviousness. Courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in the art, to modify the reference or combine the reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all claim limitations. See e.g., In re Dembiczak, 175 F.3d 994 (Fed. Cir. 1999); In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998); Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996).

In the present case, not all limitations of claims 1 and 4-22 are disclosed, taught or suggested by Lizardi and Keane, whether considered alone or in combination. The references fail to disclose, teach or suggest all limitations of amended independent claim 1. Lizardi is silent about a “suture storing device” having “a handle” and “a cavity within the handle for storing at least one strand of suture, wherein the cavity is provided with a hatch, the hatch having a tie-down bar attached on its inside, the hatch being configured to pivot, together with the tie-down bar on its inside, relative to the longitudinal axis of the elongated shaft,” as claim 1 recites.

Lizardi teaches that “suture thread retaining member 42 includes a cap member 44 and a generally cylindrical base member 46” that “is capable of retaining the suture thread 14.” (Col. 5, lines 2-4; 52-53). In this manner, the “amount of tension maintained in the suture thread 14 may be varied by opening the suture retaining member 42, pulling the thread 14 to the desired tension, and closing the suture retaining member 42 over the thread 14 to capture the thread 14 and maintain the desired tension.” (Col. 5, lines 2-4; 56-61). Thus, suture thread retaining member 42 of Lizardi is not a suture storing device, but rather is a suture retaining device – i.e.,

retaining member 42 clamps down on an intermediate portion of suture thread 14 and maintains the desired tension on suture thread 14, which is stored in internal cavity 28 (which has a slidable, not pivotable, cover member 36). In any event, Lizardi does not disclose a hatch "having with a tie-down bar attached on its inside," as recited in amended independent claim 1.

Keane fails to rectify the deficiencies of Lizardi. Keane does not disclose, teach or suggest "a cavity . . . provided with a hatch attached to the handle," much less "a cavity . . . provided with a hatch attached to the handle, the hatch having a tie-down bar attached on its inside" and "configured to pivot, together with the tie-down bar on its inside, relative to the longitudinal axis of the elongated shaft," as in the claimed invention. Keane teaches a spool system wherein "spool 1 is a cylinder shaped member, which is capable of rotating around a central axis 5" and wherein "spool 1 has several grooves 2 encircling its surface, for receiving suture thread." (§[0023]). Keane also teaches that "[t]here preferably is a separate groove 2 for each end of the suture thread being dispensed" so that "for a spool that dispenses two separate suture threads, there are preferably four grooves 2 for receiving the ends of each of the two suture threads." (§[0023]). Keane is silent, however, about "a cavity . . . provided with a hatch attached to the handle," or about "a cavity . . . provided with a hatch attached to the handle, the hatch having a tie-down bar attached on its inside" and "configured to pivot, together with the tie-down bar on its inside, relative to the longitudinal axis of the elongated shaft," as in the claimed invention. Keane teaches a novel spool system which is not a hatch, much less a hatch attached to a handle and further with the characteristics of amended independent claim 1.

Lizardi and Keane also do not disclose, teach or suggest "a cavity within the handle for storing at least one strand of suture provided with at least one surgical needle, the cavity being provided with a pivotable hatch attached to the handle, the

pivotable having a tie-down bar attached to its inside, wherein the tie-down bar is further provided with a slot for storing the at least one surgical needle, wherein the pivotable hatch is configured to be integral with the handle when the pivotable hatch is in a closed position," as claim 11 recites.

Lizardi is silent about "a cavity for storing at least one strand of suture provided with at least one surgical needle," or about "a pivotable hatch having a tie-down bar attached to its inside" or about a "tie-down bar . . . provided with a slot for storing the at least one surgical needle," as claim 11 recites. Lizardi teaches a "suture thread retaining member 42" including a cap member 44 and a cylindrical base 46 that is configured to retain a suture thread when the suture retaining member 42 is closed, and not the limitations of claim 11. Keane teaches a novel spool 1 that rotates around a central axis and has several grooves for receiving suture thread, and not the limitations of claim 11.

The cited references also do not disclose, teach or suggest all method steps of amended independent claim 19. The references are silent about "providing a suture housing device comprising . . . a cavity . . . provided with a pivotable hatch attached to the handle, the pivotable hatch having a tie-down bar attached to its inside . . . wherein the surgical suture is coiled around the tie-down bar," as in the claimed invention. Lizardi and Keane, alone or in combination, also fail to disclose, teach or suggest "actuating the pivotable hatch so that the pivotable hatch, together with the tie-down bar attached to its inside, forms an angle with respect to the longitudinal axis of the elongated shaft" and "deploying the surgical suture from around the tie-down bar."

For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 1 and 4-22 is respectfully requested.

In the November 2, 2006 Office Action, the Examiner concedes that "Lizardi does not disclose a tie-down bar" but asserts that "Keane et al. disclose a tie-down bar (Figure 3, not labeled; bar that runs through element 1) attached to a hatch (1; since the spool 1 covers an opening 13 in the handle 8)." (Office Action at 3-4). This assertion is unsupported. First, spool 1 of Keane is not a "hatch" as defined in Merriam-Webster Collegiate Dictionary, 10th Ed. ("an opening in the deck of a ship or in the floor or roof of a building") and as known to those skilled in the art. No opening is provided in spool 1 of Keane. In addition, spool 1 of Keane does not have characteristics of a hatch and is not a "covering," much less a "covering for such opening," as the Examiner asserts. (Office Action at 4). Second, the non-labeled "bar that runs through element 1" of Keane is not a "tie-down bar," much less a tie-down bar attached to the inside of the hatch, as claim 1 recites. The "bar that runs through element 1" of Keane is actually central axis 5 of spool 1 – the suture is retained in the grooves of the spool, and the axis 5 of the spool is not a tie-down bar – there is no evidence that the grooves even extend to the axis 5. Third, Keane does not disclose, teach or suggest a "cavity . . . provided with a hatch attached to the handle," much less a "cavity . . . provided with a hatch attached to the handle, the hatch having a tie-down attached to its inside," as in the claimed invention.

Allowance of all pending claims is solicited.

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